IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION

JOSHUA WILSON, *et al*	§	
	§	
Plaintiffs,	§	
	§	
v.	§	**Case No. 4:22-cv-438-ALM**
	§	
LLOYD AUSTIN, III, *et al.*,	§	
	§	
Defendants	§	

PLAINTIFFS' REPLY BRIEF TO
DEFENDANT'S OPPOSITION TO
MOTION FOR PRELIMINARY INJUNCTION

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PLAINTIFFS' REPLY BRIEF

The central thread of the government's response ("Opp."), ECF 14, to Plaintiffs' Motion for Preliminary Injunction ("PI Motion"), ECF 9, is to pretend that this is simply a case of individual, disgruntled government employees challenging unreviewable, discretionary, ongoing administrative proceedings by their employer. Plaintiffs' challenge is not simply to the (seemingly) innocuous decision of putting a "vaccine" on a list of required immunizations for the military. Plaintiff service members instead challenge a series of generally applicable, inter-related and coordinated actions by all Defendant agencies that each violated the constitutional and statutory rights of millions of service members. Further, Defendants fail altogether respond to Plaintiffs' central claims that Defendants are estopped from taking a position contrary to the one they agreed to in the 2005 Consent Decree in *Doe v. Rumsfeld*; their unlawful changes to, or violations of, their own regulations defining "vaccines" and "vaccination;" and their coordinated statutory violations to treat an unlicensed product as licensed. Accordingly, the Court must accept as true these unrebutted claims.

ARGUMENT

I. EACH CHALLENGED ACTION IS A JUSTICIABLE AND REVIEWABLE "MAJOR POLICY DECISION" OR "MAJOR QUESTION" VIOLATION.

A. The Challenged Actions.

Defendants contend that the challenged actions are non-justiciable, unreviewable, and/or due such heightened deference that any judicial review must amount to a rubber stamp approval because the Defendants' actions are matters that require the "exercise of military expertise or discretion," Opp. at 21, that the challenged actions are "committed to [agency] discretion," *id.* at

35, and/or that the "great deference to the military," *id.* at 13, "is layered on top of the deference the courts must give to expert policymakers" for "complex medical" matters. *Id.* at 31.

Plaintiffs challenge a series of discrete, final, coordinated, and unlawful agency actions by Defendants[1] to enable the illegal, *ultra vires* mandates and to discipline and discharge Plaintiffs and hundreds of thousands of similarly situated class members. Each challenged action is at a minimum a "major policy decision," rather than as Defendants' contend, a routine, "day-to-day" exercise of agency discretion, enforcement decisions, or "personnel management decisions." *Nat'l Treasury Employees Union v. Horner*, 854 F.2d 490, 496 (D.C. Cir. 1988). Each of these actions also violate the "Major Questions" doctrine insofar as they directly impose, or intentionally enable, a federal vaccine mandate, and do so not only without any express statutory authorization, *see West Virginia v. EPA,* 142 S. Ct. 2587, 2609 (2022) but in direct violation of federal statutes or the agency's own regulations.[2]

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[1] The Complaint challenges, among others: (1) the Department of Defense's ("DoD") August 24, 2021 COVID-19 "vaccine" Mandate ("DoD Mandate"); (2) Food and Drug Administration ("FDA") determinations that unlicensed COVID-19 "vaccines" subject to an Emergency Use Authorization ("EUA") are "interchangeable" with FDA-licensed vaccines (the "FDA Interchangeability Determination"); (3) the FDA's waiver of mandatory statutory labeling and informed consent requirements ("FDA Waiver"); (4) the DOD determination that EUA vaccines are legally interchangeable with, and may be mandated "as if," they were FDA-licensed vaccines ("DOD Interchangeability Determination"); (5) DOD's categorical elimination of existing medical exemptions and categorical denial of Plaintiffs' medical exemption requests ("DOD Categorical ME Ban"); (6) Health and Human Services' ("HHS") and Centers for Disease Control and Prevention ("CDC") September 1, 2021 change to the definition of "vaccines" and "vaccination" ("HHS/CDC Vaccine Redefinition"); and (7) FDA's improper approvals of Pfizer/BioNTech and Moderna's mRNA gene therapy treatments as "vaccines" ("FDA mRNA Treatment Approvals").

[2] Federal vaccine mandates are unquestionably "major questions" because they impact the lives and livelihoods of millions and impose billions of dollars in costs. *See, e.g., NFIB v. OSHA*, 142 S.Ct. 661, 668 (2022) (GORSUCH, J., concurring) ("*NFIB*") (OSHA Mandate); *BST Holdings, LLC v. OSHA*, 17 F.4th 604, 617 (5th Cir. 2021 (same); *Kentucky v. Biden*, 23 F.4th 585, 607-608

The DOD's actions—the DOD Mandate, the DOD Interchangeability Determination, and DOD Categorical ME Ban—apply to over two million service members, as well as hundreds of thousands of DOD civilian employees. Moreover, they substantially modify the terms of eligibility for enlistment, retention, deployment, promotion, completing an existing term of service, and disciplinary rules. Each DOD action easily meets the requirement for a justiciable and reviewable "major policy decision," rather than an unreviewable individual personnel or enforcement action.[3]

The challenged FDA and HHS/CDC actions also meet these requirements. Neither agency may directly impose a vaccine mandate. But the DOD Mandate—and the five other federal vaccine mandates announced by President Biden within two weeks—relied on the FDA and HHS/CDC actions to impose unlawful mandates on nearly 100 million Americans.[4]

B. Each Challenged Action Violates Express Statutory Requirements.

Congress has "plenary" power, *Bertelsen v. Cooney*, 213 F.2d 275, 276-77 (5th Cir. 1954) "to raise and support armies," U.S. Const. Art. I, § 8, cl. 12, and to "make Rules for the Government and Regulation of the land and naval forces," U.S. Const. Art. I, § 8, cl. 14, including authority to set the conditions of eligibility for service, accession, and retention. *See, e.g., United States v. Williams*, 302 U.S. 46 (1937). While Congress has undoubtedly granted DOD and the Service Secretaries the authority to enact measures regarding the "morale and welfare of personnel," 10

(6th Cir. 2022 (federal contractor mandate); *see also Health Freedom Def. Fund v. Biden*, 2022 WL 1134138, at *10 (M.D. Fla. Apr. 18, 2022) (vacating CDC transportation mask mandate).

[3] *See, e.g., Harrison v. Austin*, 2022 WL 1183767, at *11 (E.D. Va. Apr. 6, 2022) ("*Harrison*") (rejecting justiciability, reviewability, and military deference arguments and finding that for DoD deployment policy for HIV-positive service members based on "major policy decisions" doctrine).

[4] All five of these mandates—the Federal Employee Mandate, Federal Contractor Mandate, the OSHA Mandate, the Head Start Mandate, and the Healthcare Work Mandate—were stayed for the same statutory violations as alleged by Plaintiffs. *See* ECF 9, ¶ 5 & nn.3-4.

U.S.C. §7013(b)(9), §8013(b)(9), §9013(b)(9), it has not precluded judicial review of those measures, nor has it authorized DOD to violate the Constitution, express federal statutory prohibitions, or its own regulations in implementing such measures, and Defendants have not shown otherwise.

Secretary Austin's Mandate and the other challenged agency actions may result in the loss of up to 300,000 service members.[5] They are also directly responsible for massive recruiting shortfalls, with the Army having reached only 40% of its FY22 target with less than three months left.[6] A significant cause of the recruiting shortfall is that the new requirement eliminates roughly one-third of potential recruits in the 18-29 age range solely because they are unvaccinated. As a result, the Army will fall short of its FY22 end strength goal by nearly 20,000 for this year and by up to 57,000 for 2023,[7] and will for the first time in two decades fall under 1,000,000 total active-duty, reserve and national guard.[8] The loss of current personnel and future recruits are so great that

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[5] This includes at least 25,000 who have submitted religious accommodation requests, *see* Compl., ¶¶ 102-105 & Table, and nearly 270,000 service members who are partially-, but not fully-, vaccinated as of July 13, 2022. *See* DoD. *Coronavirus: DOD Response*, Table: DOD Vaccination Data, available at: https://www.defense.gov/Spotlights/Coronavirus-DoD-Response/ (last visited July 19, 2022).

[6] *See* Courtney Kube & Molly Boigon, *Every Branch of the Military is Struggling to Make its 2022 Recruiting Goals, Official Say*, NBCNews (June 27, 2022), available at: https://www.nbcnews.com/news/military/every-branch-us-military-struggling-meet-2022-recruiting-goals-officia-rcna35078 (last visited July 17, 2022).

[7] *See* John M. Donelly, *Army Tells House Panel of Enormous Personnel Shortfalls*, Roll Call (July 19, 2022), available at: https://rollcall.com/2022/07/19/army-tells-house-panel-of-enormous-personnel-shortfalls/ (last visited July 20, 2022).

[8] *Id.* This number does not account for the over 60,000 Army reserve and National Guard who were effectively discharged by being placed into the IRR just this month. *See* Allie Griffin, *Army Bars More Than 60K National Guards, Reservists from Service, Cutting Off Pay*, NY Post (July 8, 2022), available at: https://nypost.com/2022/07/08/army-cuts-pay-from-over-60k-unvaccinated-national-guard-reserves/ (last visited July 17, 2022).

they many worry that they create a "long-term threat to the all-volunteer force."[9]

The DOD Mandate is not a routine or discretionary health and welfare measure, but rather an "attempt to usurp major policy decisions properly made by Congress." *NLRB v. South Cent. Bell Telephone Co.*, 688 F.2d 345, 351 (5th Cir. 1982) (quotation marks omitted). Congress has not delegated to Secretary Austin the authority to adopt major new policies that will result in the loss of hundreds of thousands of service members, causing each of the Services to fall below Congressionally mandated levels, at a time where we face multi-front war with peer competitors like Russia and China. Nor has Congress delegated to Secretary Austin the authority to mandate an unlicensed vaccine; in fact, it has expressly *withheld* such authority, twice, for both Investigational New Drugs (INDs) and EUAs in 10 U.S.C. §§1107 & 1107a.

The FDA Waiver goes well beyond enforcement discretion because it violates mandatory labeling provisions of federal statutes it implements and its own regulations, and effectively granted a waiver not permitted or even contemplated by Congress.[10] Similarly, the FDA Interchangeability Determination ignored entirely the PHSA's intricate procedures and requirements for a statutory interchangeability determination and instead made the determination

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[9] Tom Jurkowsky, *The Military Has a Serious Recruiting Problem – Congress Must Fix it*, The Hill (June 21, 2022) (*quoting* Sen. Thom Tillis (R-N.C.)), available at: https://thehill.com/opinion/national-security/3527921-the-military-has-a-serious-recruiting-problem-congress-must-fix-it/ (last visited July 17, 2022). *See also supra* note 6, Kube & Boigon ("2022 is the year we question the sustainability of the all-volunteer force").

[10] *See* ECF 9 at 35-36 (discussing FDA violations of the Public Health Safety Act ("PHSA") and *Beaty v. FDA,* 853 F.Supp.2d 30, 36 (D.D.C. 2012), *aff'd in part, vacated in part sub. nom. Cook v. FDA*, 733 F.3d 1 (D.C. Cir. 2013); *see also Alliance for Bio-Integrity v. FDA*, 116 F.Supp.2d 166 (D.D.C. 2000) ("*Alliance for Bio-Integrity*") (FDA policy not to enforce requirements against a whole category of products or "not to regulate an entire class of conduct" was a "major policy decision" that exceeded enforcement discretion and was subject to review and therefore was not immune from review for actions "committed to agency discretion").

by dropping footnotes in its order. *See id.* at 36-37. These actions affirmatively conferred a legal benefit and a heightened legal status—in Defendant FDA and DOD's view converting an unlicensed EUA vaccine into FDA-licensed vaccine—that was relied on by DOD and other federal agencies to impose illegal vaccine mandates on over 100 million Americans. Defendants offer no response to these arguments or even cite any legal basis for the HHS/CDC Vaccine Redefinition.

C. Defendants' Actions Are Justiciable and Reviewable.

Exceptions to judicial review are "very narrow" and "reserved for those rare instances where the relevant statute is drawn so that a court would have no meaningful standard against which to judge the agency's exercise of discretion." *Weyerhauser Co. v. U.S. Fish and Wildlife Servs.*, 139 S. Ct. 361, 370 (2018) (citation and quotation marks omitted). The DOD actions are justiciable or reviewable because, in addition to being illegal, they are "high-level policy decisions 'made far from the field of battle,'" and not uniquely military in nature at all.[11]

The Informed Consent Laws and PHSA each contain express statutory prohibitions and commands that provide meaningful standards for review: (1) 10 U.S.C. § 1107a prohibits the mandate of EUA products without Presidential authorization; (2) 21 U.S.C. § 360bbb-3 requires, without exception, that recipients of an EUA products be informed "of the right to accept of refuse the product" in the EUA factsheet included in the labeling of all EUA products; and (3) 42 U.S.C.

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[11] *Harrison*, 2022 WL 1183767, at *12 (*quoting Zaidan v. Trump*, 317 F.Supp.3d 8, 22-23 (D.D.C. 2018). *See also id.* (rejecting application of *Doe v. Sullivan*, 938 F.2d 1370 (D.D.C. 1991)). Indeed, by refusing to certify that there is any threat to national security under §1107a, the government has forfeited any claim to "national security" prerogatives in this litigation. COVID-19 is either a national security matter or it isn't; if it is, then the President and Defendant DOD have a statutory vehicle for that claim to mandate unlicensed products to the Force, yet they refuse to do so.

§§ 262(a) and (k) are both mandatory, non-waivable requirements for labeling and licensure of biologic products and for a product to be deemed "biosimilar" or "interchangeable."

II. THIS COURT HAS SUBJECT MATTER JURISDICTION

A. The Availability of Comirnaty Does Not Deprive Court of Jurisdiction.

Sometime after Plaintiffs filed the Complaint on May 23, 2022, Defendant DOD for the first time supposedly obtained a limited quantity of FDA-licensed and labeled Comirnaty more than nine months after the Comirnaty was licensed and the DOD Mandate was announced. In Defendants' view, the purported availability of Comirnaty and their offer of same to Plaintiffs means that Plaintiffs lack standing for their statutory claims, which have been rendered moot. Opp. at 24-25. Both claims are incorrect.

It is undisputed that: (1) no Comirnaty was available from the issuance of the Mandate in August 24, 2021 through at least the date that the Complaint was filed;[12] (2) DOD considered FDA-licensed and labeled vaccines as "legally interchangeable" with EUA vaccines, which could be mandated "as if" they were FDA-licensed and labeled vaccines from the date of the DOD Mandate through the present;[13] (3) all Plaintiff injuries alleged in the Complaint occurred during

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[12] It is not clear precisely when DOD was able to begin administering the Comirnaty doses it has obtained to service members. DOD states that, on May 20, 2022, "Pfizer-BioNTech's Comirnaty-labeled vaccine became available for ordering." 14-2, ¶ 19. As of July 15, 2022, the date of their filing, "DOD has received over 42,000 doses." *Id.* DOD does not allege that it had received any doses as of the date of filing of the Complaint, but it is reasonable to assume that no doses had been received until at least early to mid-June when Defendants first made the offer to Plaintiffs.

[13] The availability of FDA-licensed and labeled Comirnaty has no legal significance for Defendants. They have insisted from the outset through the present that EUA and FDA-licensed vaccines are legally interchangeable and that EUA vaccines may be mandated "as if" they were the FDA-licensed vaccines. *See generally* Compl., ¶¶ 184-197. The availability of Comirnaty does, however, demonstrate another gross statutory violation of the EUA statute, which requires revocation of the EUA when licensed products are available. *See* Compl., ¶¶ 58, 68 & 21 U.S.C. § 360bbb-3(a)(2)(A) & (b)(2)(A) (the EUA for a product "shall terminate" when the product is

the when the DOD unlawfully mandated EUA vaccines; and (4) Defendant DOD has disciplined Plaintiffs (and discharged similarly-situated class members) for refusal to take EUA vaccines.[14] Further, there are not sufficient quantities of Comirnaty for un- or partially vaccinated members.[15]

Accordingly, Defendants' offer does not affect Plaintiffs' standing because it does nothing to eliminate or redress Plaintiffs' existing injuries due to noncompliance with the Mandate to take an EUA vaccine. Nor will it preclude any future injuries because the DOD had not rescinded or altered its policy, and due to the insufficient quantities available, the vast majority of Plaintiffs and class members would have to take an EUA vaccine to comply with the DOD Mandate.[16]

Even if this Court were to decide that the availability of small and insufficient quantities of Comirnaty could moot Plaintiffs' statutory claims, their claims "would avoid mootness" due to "the presence of an issue capable of repetition, yet evading review" because: (1) "the challenged action was too short to be fully litigated before its cessation or expiration, and (2) there [is] a reasonable expectation that [Plaintiffs will] be subjected to the same action again." *Fla. Bd. of Bus.*

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approved). Now that the licensed Comirnaty is "available" Defendant FDA cannot continue to maintain the EUA in force, a clear violation of a statutory mandate reviewable by this Court.

[14] Plaintiffs have responded to Defendants' general offer with a list of questions seeking clarification as to whether DOD or the Service branch will make any binding, legally enforceable commitments to redress Plaintiffs' injuries from refusal to take an EUA vaccine or not to pursue further discipline or discharge. Defendants have not yet responded.

[15] Comirnaty is not available in sufficient quantities to provide to the eligible population. The stock of 42,000 doses is sufficient for 21,000 service members. Based on publicly available information, it appears that there are at least 100,000 unvaccinated service members, and an additional 270,000 partially vaccinated service members, so the existing supply is sufficient for 5-10% of service members so that 90-95% of this population would be required to take an EUA vaccine.

[16] While it is not clear if Defendants' challenge ripeness, Plaintiffs' statutory claims are ripe. For ripeness, the test is whether "the suit was ripe when it was filed." *Blitch v. City of Slidell*, 260 F.Supp.3d 656, 662 (E.D. La. 2017). It is undisputed that Comirnaty was not available, *i.e.*, not in DoD's possession for administration to service members, when the suit was filed on May 23, 2022.

Regul. v. N.L.R.B., 605 F.2d 916, 920 (5th Cir. 1979) (citation and quotation marks omitted). Defendants consistent and current policy is that EUA vaccines may be mandated, and they have not renounced or reversed that policy formally or informally. These violations will continue in the future both for current Mandate due to insufficient supply and almost certainly in the future due to the likely imposition of requirements for EUA boosters and/or new variant-specific vaccines.[17]

Plaintiffs' claims also qualify for the "voluntary cessation" exception to mootness.[18] Defendant DOD maintains the EUA mandate in force, and it only agreed to pause enforcement of the mandate while the PI Motion is being briefed by the Court (in exchange for Plaintiffs' agreement not to file TRO), while insisting that the underlying policy is legal.

Finally, equity demands that Plaintiffs be permitted to move forward to obtain the relief they request without regard to what Defendant DOD has done. Plaintiffs seek a determination as to whether or not the gene therapy treatments being forced on them are properly licensed as "biologics" (vaccines) subject to the PHSA or instead are subject to the FDCA. Further, the FDA's

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[17] New EUA mandates are likely because: (1) the currently mandated two-dose regimen "offer[s] little, if any, protection" from Omicron, 49-1, ¶ 20; (2) Defendant FDA and HHS/CDC recommends that all adults should receive EUA booster shots, which Defendant DOD purports to treat as binding, *see* Compl.¶ 202; (3) to show vaccine efficacy against Omicron, Defendants heavily rely on the results for those who have received booster shots, *see, e.g.,* ECF 14-1, ¶¶ 17-18, 20; ECF 14-2, ¶¶ 17, 32, 36; (4) FDA and CDC recommendations regarding variant-specific vaccines, all of which will necessarily be EUA, FDA, *FDA Recommends Inclusion of Omicron BA.4/5 Component for COVID-19 Vaccine Booster Doses* (June 30, 2022), available at: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-recommends-inclusion-omicron-ba45-component-covid-19-vaccine-booster.

[18] *See, e.g., Sossaman v. Lone Star State of Texas*, 560 F.3d 316, 325 (5th Cir. 2009) ("[i]t is well settled that a defendants' voluntary cessation of a challenged practice does not deprive a federal court of its power to determine the legality of a practice") (citations and quotation marks omitted); *K.P. v. LeBlanc*, 729 F.3d 427, 438 (5th Cir. 2013) ("a defendant cannot automatically moot a case simply by ending its [challenged] conduct once sued.")(citation and quotation marks omitted).

requirements for licensing and EUAs are mutually exclusive; the same product—or same vial of vaccine—cannot simultaneously be granted an EUA and licensed for the same indication or use.[19] That is by design because the FDA's charter – it's very *reason for being* – is to protect the public against the harms that could result from inadequately tested and regulated products being distributed *en masse* to an unsuspecting public.

B. Plaintiffs' Claims Against DOD Are Justiciable.

Defendants' assertion that claims "challenging military assignment, training, schooling, promotion and other operational decisions ... are nonjusticable," Opp. at 19, is contrary to the very authority on which they rely.[20] *Orloff v Willoughby*, 345, U.S. 83 (1953) addressed a petition by a doctor drafted under the "Doctors Draft Act" claim he was entitled to a commission and assignment to a doctor's position. The Court held that failure to assign Orloff duties for which he was drafted, *i.e.*, a doctor, would raise justiciable "questions not only of bad faith but of unlawful discrimination." *Id.* at 88. The Court's admonition about judicial noninterference specifically referred to "legitimate Army matters." *Id.* at 94. Operating contrary to the Constitution is not a *legitimate* matter, and it is in the Court's power to address constitutional violations in such personnel policies. *See, e.g., Emory v. Secretary of Navy*, 819 F.2d 291, 294 (D.C. Cir.1987).

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[19] *See, e.g., Genus Med. Techs. LLC v. FDA*, 994 F.3d 631 (D.C. Cir. 2020) (holding that the FDA's determination that it could choose to regulate a product as either a drug or a device, or both, was arbitrary and capricious and exceeding its statutory authority).

[20] Defendants consistently conflate justiciability with the scope of preliminary relief that may be granted. *See, e.g.,* ECF 14 at 19-20. Defendants' claims regarding the non-justiciability of these issues rely on Justice Kavanaugh's lone concurrence in *Austin v. Navy SEALs 1-26*, 142 S.Ct. 1301 (2022). *See* ECF 14 at 20. There, the Supreme Court limited the scope of the preliminary relief but left in place the district court and the Fifth Circuit's findings that the plaintiffs' RFRA and First Amendment claims were justiciable, ripe, and satisfied all factors for a preliminary injunction.

With respect to the *Mindes* criteria, Plaintiffs' claims do not interfere with military functions nor require military expertise. Plaintiffs' claims largely seek to require DOD to follow its own regulations. *See* Ex. 1 DODI 6200.02 (EUA/Informed Consent rights), ECF 9-3 DODI 6205.02 (definitions of "vaccine" and "vaccination") and AR 40-562 (medical exemptions). "Requiring the military to follow its own policies does not interfere with its functions." *Roe v. Esper*, 947 F.3d 207, 218 (4th Cir. 2020) ("*Roe*"). By adopting the DOD Categorical ME Ban, the DOD "declin[ed] to make individualized determinations regarding servicemembers' fitness for service," and thereby "failed to apply its expertise to the evidence before it." *Roe*, 947 F.3d at 218.

C. Plaintiffs Have Standing.

Defendants' claim that Plaintiffs cannot establish Article III standing because they do not face "involuntary vaccination" or physical injury. ECF 14 at 17 & n.21.[21] First, Plaintiffs challenge a vaccination m*andate*, which is by definition *involuntary*. Defendant DOD has applied the full range of disciplinary and coercive measures permitted by the UCMJ – and even some not allowed – to enforce compliance.[22] Plaintiffs' claims are identical to those raised against the anthrax

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[21] Defendants erroneously suggest that named Plaintiff class representatives wish to assert third-party or associational standing on behalf the MAFL Members. *See* Opp. at 10 n.18. This is incorrect. MAFL Members are Plaintiffs and parties and were included in the May 23, 2022 Complaint. Moreover, Plaintiffs' counsel have already sent opposing counsel a list of the ~750 members who wish to intervene as part of the meet and confer obligation. So as not to interfere with the current briefing schedule, and give opposing counsel adequate time to prepare a Response, Plaintiffs' counsel will file the Motion to Intervene on Tuesday, July 26, 2022.

[22] As just one example, most plaintiffs have been restricted to within 50 miles of their base for normal leave and liberty for the past nine months and are subject to prosecution under Art. 92, UCMJ, for traveling outside of that radius. Unvaccinated Plaintiffs are also publicly identified (in violation of HIPAA), and publicly shamed – in derogation of Art. 13, UCMJ. Some have been prohibited from using the mess halls to dine with their colleagues. The Coast Guard has gone so far as to make it a policy to treat the unvaccinated as a threat to their commands, colleagues, families, and the country at large. *See, e.g.*, ALCOAST 315/21 ("Given the need to safeguard the workforce, and maintain readiness, the Coast Guard will determine additional measures to mitigate

vaccine mandate (an actual vaccine) successfully challenged in the *Doe v. Rumsfeld* cases where the court found that the mandate cause injury sufficient for standing as well as irreparable harm.[23] With respect to physical injury, Plaintiffs' allegations are based on evidence compiled by Defendants themselves of significant risks of death or permanent injury that far outweigh the benefits of the treatment versus and the risks from Omicron. *See* Compl., ¶¶ 116-118 (safety data).

Defendants also erroneously assert that Plaintiffs lack standing as to their claims against the FDA.[24] The court there found that the Plaintiffs failed to show causation and redressability because the FDA was the sole defendant so that Plaintiff's injury from the DOD Mandate "results from the independent action of some third party [*i.e.*, DOD] not before the court." *CHD I*, at *6. Here, all the agencies necessary to grant the relief sought are parties to this proceeding. With respect to traceability and redressability, the FDA and HHS/CDC actions are the proximate and "but for" cause of the DOD Mandate. The DOD Mandate permits only FDA-licensed and labeled vaccines to be mandated; yet without the challenged FDA actions, which convert an unlicensed product to a licensed one, the DOD could not have mandated EUA vaccines. Accordingly, an order of the against the FDA can redress those injuries and potentially stop the Mandate itself.[25]

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health risks to members of the Service and our communities *posed by those who are not yet vaccinated*. These measures may include additional restrictions on official travel, liberty, and leave, as well as cancellation of… orders…")

[23] *John Doe No. 1 v. Rumsfeld*, 297 F. Supp. 2d 119, 135 (D.D.C. 2003) ("*Rumsfeld I*"), *modified sub nom. John Doe No. 1 v Rumsfeld*, 341 F. Supp. 2d 1 (D.D.C. 2004) ("*Rumsfeld II*"), *modified sub nom. John Doe No. 1 v. Rumsfeld*, 2005 WL 774857 (D.D.C. Feb. 6, 2005) ("*Rumsfeld III*").

[24] *See* Opp. at 24-25 (*citing Children's Health Defense Fund v. FDA*, 2021 WL 5756085 (E.D. Tenn. Nov. 30, 2021) ("*CHD I*"), *aff'd*, 2022 WL 2704554 (6th Cir. July 12, 2022) ("*CHD II*").

[25] *CHD II* holds that the DOD "can require vaccination regardless of whether the vaccine is distributed pursuant to a license or EUA." *CHD II*, at *4. 10 U.S.C. § 1107a prohibits the DoD from mandating EUA treatments; it does not purport to address distribution. This statement is driven by the fact that DOD was not a party. The Court's other bald claims about DOD are

D. Plaintiffs' Claims Are Ripe.

Plaintiffs here challenge an inter-related series of discrete, final, and coordinated agency actions adopting generally applicable rules, regulations, and policies, *see supra* note 1, that: (1) represent the consummation of the agency's decision-making process; (2) have been consistently implemented since the adoption of the DOD Mandate through the present; (3) determine Plaintiffs' legal rights and obligations; and (4) are the legal basis and proximate cause for Plaintiffs' injuries. *See* ECF 9 at 13-14 & *supra* Section II.A. Plaintiffs do not, as Defendants' claim, challenge discrete, individual personnel actions such as a Board or discharge proceeding. Opp. at 18.

Defendants seek to conflate the fitness criteria (finality, definiteness, need to develop factual record) with the injury analysis. The challenged agency actions are *generally* applicable rules that have been directly applied to, and enforced against, Plaintiffs, and hundreds of thousands of similarly-situated class members, in the exactly the same way. They are now "legal question[s]" ripe for review that "will foster rather than impede final resolution of this matter." *State of La. v. Dept. of Energy*, 507 F.Supp.1365, 1374 (W.D. La. 1981). The court need not await completion of individual administrative proceedings, which are not challenged, to rule on the ones that are.

Plaintiffs' past and ongoing injuries easily satisfy the hardship prong. *See* ECF 9, ¶ 6 (summarizing Plaintiff declarations). Indeed, one of the named Plaintiffs, Col Karyn Christen, USAFR, was forced to retire during the pendency of this case. Plaintiffs face the imminent threats of separation proceedings for *misconduct*, discharge for *misconduct*, forced retirement, or placement into the IRR; these actions have only been averted by the class-wide injunctions for

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necessarily dicta because it addresses the rights and obligations of the DOD thereunder, a party *not* before the Court.

Navy and Air Force members[26] and Defendant DOD's agreement to pause such proceedings until this Court acts on Plaintiff's PI Motion. A stay or injunction does not "negate otherwise-existing standing and ripeness." *Texas v. Brooks-LaSure*, 2021 WL 5154219, at *4 (E.D. Tex. Aug. 20, 2021). If the PI Motion is denied, or the class-wide preliminary relief for Navy and Air Force members is lifted, enforcement against Plaintiffs' will recommence immediately. This is not speculation; this is DOD policy that they have been carrying out regularly.

III. PLAINTIFFS CAN DEMONSTRATE A LIKELIHOOD OF SUCCESS.

A. Plaintiffs Will Prevail on Their Constitutional Claims.

For Plaintiffs' constitutional claims the central questions are "[w]ho decides," *NFIB v. OSHA*, 142 S.Ct. at 667 (GORSUCH, J., concurring) what a "vaccine" is, and "which authorities," *id.*, may impose "vaccine" mandates. Courts do no defer to an agency that has exceeded its statutory authority and/or violated federal statutes or its own regulations in an "attempt to usurp major policy decisions properly made by Congress," *NLRB*, 688 F.2d at 351, or state legislatures. Instead, courts review the agency's legal interpretation of the governing statute because such actions are not matters "peculiarly within the agency's expertise and discretion." *Crowley Caribbean Transp., Inc. v. Pena*, 37 F.3d 671, 677 (D.C. Cir. 1994).

In any case, there is nothing to which the Court can defer on these key questions.[27] Defendants simply dismiss the September 1, 2021 HHS/CDC Vaccine Re-Definition by stating

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[26] *See Navy SEALs 1–26 v. Austin*, No. 4:21-cv-1236, 2022 WL 1025144 (N.D. Tex. Mar. 28, 2022) (Navy class-wide preliminary injunction), *appeal filed* No. 22-10534 (5th Cir. May 27, 2022); *Doster v. Kendall*, --- F.R.D. ---, 2022 WL 2760455 (S.D. Ohio July 14, 2022) (Air Force class-wide temporary restraining order issued July 14, 2022, and set to expire on July 28, 2022).

[27] Defendants fail altogether to substantively address Plaintiffs' challenges to Defendants' determination that the Pfizer/BioNTech and Moderna mRNA treatments are not "vaccines;" that the FDA miscategorized and approved as biologics, instead of as a treatment, or that mRNA

that Plaintiffs "do not explain how that would inform judicial scrutiny." Opp. at 28 n.25. This is simply false. The bulk of the discussion of Plaintiffs' Substantive Due Process claim in the PI Motion addressed the significance of the CDC change to the definition, ECF 9 at 16-21, explaining that the level of scrutiny is determined by whether the mandated products are treatments, subject to strict or heightened scrutiny,[28] or vaccines subject to rational basis review under *Jacobson v. Massachusetts*. Nor do Defendants identify any legal basis that would authorize the DOD to ignore its own regulations or for HHS and CDC to arbitrarily expand the definition of "vaccines" and "vaccination" for the sake of its preferred policy outcomes (*i.e.*, enabling federal vaccine mandates). In the absence of any rebuttal, Plaintiffs should be deemed to have carried their burden of proof on these issues and preclude any deference to Defendants' unexplained actions.

In support of their response, Defendants have submitted hundreds of pages of testimony and dozens of declarations (but no expert witness testimony)[29] by military officers. Some of these

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treatments cannot be a vaccine as defined by DODI 6205.02 or the CDC's pre-September 2021 definition. *See* ECF 9 at 14-16. Defendants also fail respond to the second question—"which authorities" may impose a vaccine mandate, a state legislature's police power mandate as in *Jacobson*, or a federal administrative mandate of a COVID-19 treatment—or to address any of the other differences between the *Jacobson* mandate the DOD Mandate.

[28] Defendants assert that "Plaintiffs provide no authority that policies requiring 'treatments' receive higher scrutiny than policies requiring 'vaccines.'" Opp. at 28. While this statement is false, it reveals Defendant's position ***that any medical treatment, not just vaccines, may be mandated for anybody***. Defendants cite no authority whatsoever for this expansive assertion of unbridled power over service members and citizens alike. Defendants' suggestion that Plaintiffs "can also take a non-mRNA vaccine … to satisfy the vaccination requirement," *id.*, is irrelevant because these non-mRNA vaccines are also *unlicensed, EUA products* and cannot be mandated.

[29] Defendants do not claim that any of their declarants are providing expert witness testimony, nor do they provide the declarants' CVs listing publications or cases in which they have provided such testimony or other evidence the declarants are qualified as experts on the subjects of their testimony. Moreover, all declarants are military officers employed by, or ultimately under the direction of, Defendant DOD and any testimony provided is at the command of Defendant DOD. Their opinions and conclusions cannot be deemed to have been formed independent of DOD

declarations, in particular those provided by Major Scott Stanley, ECF 14-1, and Colonel Tanya Rans, ECF 14-2, discuss or cite studies by academic or federal agencies, but the cited studies have little or no bearing on the salient issues here, namely: (1) the relative risks posed or faced by vaccinated vs. unvaccinated service members from current Omicron sub-variants; and (2) the protection provided by the mandated two-dose mRNA regimen vs. natural immunity.[30]

For the purposes of Court's review, Plaintiffs wish to highlight the following undisputed facts. First, no active-duty service member, whether vaccinated or not, has died since November 2021 when the Omicron variant became prevalent. *See* ECF 14-2 at 12-13 & Table. Second, the Defendant HHS' own data shows that the treatment for the virus has killed more service members (119) than the virus itself (96), and in a much shorter time period. *See* ECF 9 at 11 & n.18 & Opp. at 30. Third, Pfizer's CEO, the *New England Journal of Medicine*, and apparently Defendants acknowledge that the mandated two-dose regimen "offer[s] little, if any protection against [Omicron] infection."[31] Fourth, the military will lose hundreds or even thousands to discharge for each live lost to COVID, *see supra* Section I.B.

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influence. Plaintiffs by contrast have provided the unrebutted expert witness testimony of Dr. Peter McCullough with the Complaint. *See generally* ECF 3-2, McCullough Decl., ¶¶ 2-6 & Ex. 2, Dr. Peter McCullough CV. Applicants have also provided in Ex. 3 the Declaration of Jayanta Bhattacharya.

[30] The studies suffer from one or more of the following defects: (1) they address the past 2.5 year period, consider periods prior to the development of vaccines or vaccine deadlines, and/or the emergence of Omicron; (2) they are not limited to service members; (3) the time series statistics provided do not provide a breakdown of vaccinated vs. unvaccinated service members, in particular the Rans Declaration Table, *see* ECF 14-2 at 12-13 & Table; and/or (4) for nearly all recent studies that do address Omicron they consider the addition of one or more boosters, rather than the mandated two-dose regimen.

[31] ECF 14-1, ¶ 20. *See also New COVID-19 Vaccine That Covers Omicron 'Will Be Ready in March,' Pfizer CEO Says* Yahoo!Finance (Jan. 10, 2022) (transcript of video interview with Pfizer

Defendants' legal interpretation cannot survive even rational basis review once deference is stripped away. For such major policy decisions, courts apply a more searching, and non-deferential, version of rational basis review in which they independently weigh the evidence and assess whether the action furthers the asserted policy or is instead an improper pretext.[32]

Plaintiffs have already demonstrated at length in the Complaint and PI Motion that the stated purposes of "military readiness" and "health and welfare" are pretexts for improper and unlawful motives, *see* ECF 9 at 23-25, and that Secretary Austin's actions are arbitrary and capricious in violation of both the APA and the Equal Protection Clause. *See* Compl., ¶¶ 199-210; ECF 9 at 37-39. The evidence provided in Section I.B and in this section conclusively that the DOD Mandate and other challenged actions have no rational basis and have precisely the opposite effect of the stated purpose: the "(non)cure" has already killed more service members than the disease it is supposed to treat. Rather than promoting military readiness, these policies will destroy it, resulting in the loss of hundreds of thousands of service members and threatening the viability of the All-Volunteer Force.[33]

CEO Albert Bourla), available at: https://finance.yahoo.com/video/covid-19-vaccine-covers-omicron-144553437.html (last visited July 17, 2022).

[32] *See, e.g., Harrison*, 2022 WL 1183767, at *12-14 (weighing scientific evidence in finding DOD deployment policy failed rational basis review). For equal protection claims, rational basis review is "fundamentally indistinguishable" from arbitrary and capricious review under the APA. *Grant Med. Ctr. v. Hargan*, 875 F.3d 701, 708 (D.C. Cir. 2017); *see also Conner v. Alltin, LLC*, --- F.Supp.3d ---, 2021 WL 5588731, at *13 (N.D. Miss. Nov. 30, 2021) ("arbitrary and capricious classification … violates the Equal Protection Clause").

[33] The same analysis applies to the DOD Categorical ME Ban and rejection of natural immunity also fails rational basis review. The evidence available demonstrates that for the currently prevalent Omicron variant, natural immunity provides superior protection to vaccination. *See* ECF 39-1, ¶ 20 (50% for natural immunity while two-dose mRNA treatment "offer[s] little, if any, protection"); *see also* Ex. 1, Dr. Bhattacharya Decl., ¶¶ 17-34 (discussing studies finding that

B. Plaintiffs Will Prevail on Statutory Informed Consent Claims.

Defendants ignore the merits of Plaintiffs' statutory claims (*i.e.*, violations of APA and PHSA), with the exception of 10 U.S.C. § 1107a, which they assert is merely a "notification requirement,"[34] *i.e.*, a right to receive a package insert informing them of their statutory right to accept or refuse the EUA product. In other words, "telling them that they have the 'option' to refuse the COVID-19 vaccine if they effectively lack such an option because of a military order." ECF 5-14 at 18.[35] To call this sophistry would be unfair to sophists. Defendant agencies themselves rejected DOJ defense counsel's absurd interpretation at the time of enactment, as reflected in the *Rumsfeld III* consent decree, *see* ECF 9 at 31-33, and this remained the DOD's consistent position until at least July 2021. These "established practice[s]" are not only due greater deference than sudden, unexplained reversals, *see BST*, 17 F.4th 604, but the long-standing and consistent refusal to exercise a claimed power is "significant in determining whether such a power was actually conferred." *West Virginia*, 142 S. Ct. at 2610 (citation and quotation marks omitted). Defendants

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natural immunity provides stronger and more durable protection against Delta and Omicron variants than vaccination).

[34] Opp. at 34. Defendants also argue that Plaintiffs have "no private right of action" against the FDA for violations of 21 U.S.C. § 360bbb-3. Opp. a 35 (*citing Navy SEAL 1 v. Biden*, --- F. Supp. 3d ---, 2021 WL 5448970, at *3 (M.D. Fla. Nov. 22, 2021) ("*Navy SEAL 1*"). Plaintiffs' right of action is provided by the APA, *i.e.*, they were harmed by the FDA's violations of their statutory rights, which provides a right of action for those harmed by agency action and do not have an express right of action under the statute violated. *See* 5 U.S.C. §§ 702, 704, 706(2)(C). The plaintiffs in *Navy SEAL 1* did not assert APA claims.

[35] Defendants' current interpretation of 10 U.S.C. § 1107a was first articulated in the July 6, 2021 Office of Legal Counsel Memorandum. ECF 5-14. There, the DOD indicated that it "has understood section 1107a to mean that DOD may not require service members to take an EUA product," as reflected in DOD regulations. *See* Ex. 1, DOD Instruction 6200.02, § E3.4 (Feb. 27, 2008) (under the EUA statute, "potential recipients are provided an option to refuse administration," but "the President may . . . waive the option to refuse").

are estopped by the consent order in *Rumsfeld III* from arguing a contrary position, at least for those Plaintiffs and class members who were covered by that DOD-wide injunction.

IV. PLAINTIFFS HAVE SUFFERED IRREPARABLE HARM.

Defendants contend that Plaintiffs cannot show that they will be irreparably harmed absent preliminary relief because Plaintiffs will not be "involuntarily" injected, Opp. at 37, the harms alleged are speculative, "remote" and not "imminent," *id.* at 37-38, and that a military discharge alone cannot constitute irreparable harm. *Id.* Defendants' claim that the DOD Mandate is voluntary was disposed of Section **Error! Reference source not found.** above. Plaintiffs face imminent harm if the PI Motion is not granted. As noted above, DOD agreed to a temporary "pause" of disciplinary and separation proceedings. Defendants' voluntary cessation of enforcement does not preclude irreparable harm. *See, e.g,. Meltzer v. Bd. of Pub. Instruction,* 548 F.2d 559, 566 n. 10 (5th Cir.1977), *cert. denied,* 439 U.S. 1089 (1979). Nor does *Navy SEALs 1-26* injunction or the *Doster* TRO, which expires July 28 because Plaintiffs come from services not covered by any such order.

While a general discharge alone may not constitute irreparable injury, it may where the "circumstances surrounding … discharge, together with the resultant effect on the employee … so far depart from the normal situation that irreparable injury may be found." *Sampson v. Murray*, 415 U.S. 61, 90, 94 S.Ct. 937 (1974). Irreparable harm occurs where, as here, service members will be "discharge[d] without an individualized assessment of their fitness for continued service and for reasons unrelated to their ability to service," coupled with a discharge with a misconduct characterization that they will have to disclose along with their unvaccinated status, injuries that cannot be "address[ed] … through post-discharge intra-service procedures." *Roe*, 947 F.3d at 218. Plaintiffs and class members risk loss of retirement eligibility with more than 15 years of service,

or being dropped into the IRR, resulting in irreparable harm from the loss of military medical insurance for themselves and family members, *see, e.g., Camacho v. Texas Workforce Comm'n*, 326 F.Supp.2d 794, 802 (W.D. Tex. 2004), who have endured decades of deployments, missed births, birthdays, and anniversaries.

V. BALANCE OF EQUITIES AND PUBLIC INTEREST FAVOR GRANTING PRELIMINARY INJUNCTION.

Plaintiffs simply ask that this Court perform its assigned role, and duty, to interpret and enforce constitutional rights and "to determine whether those rights have been violated." *Emory*, 819 F.2d at 294. Here, there is no conflict between the public's "exceptionally strong interest in national defense," Opp. at 38, and Plaintiffs' constitutional rights. The most effective way to promote the public interest generally and the specific interest in strong national security is to enforce Plaintiffs Constitutionally protected liberties. It is Defendants' systematic violations of constitutional rights that threaten national security. Defendants' imposition and enforcement of an unlawful vaccine mandate threatens to purge hundreds of thousands of service members, is destroying recruitment, and even threatens the viability of the AVF. *See supra* Section I.B.

VI. CONCLUSION

This Court should grant the preliminary injunction enjoining Defendants from violating Plaintiffs' constitutional and statutory rights, as set forth in the Proposed Order.

Dated: July 22, 2022

Respectfully submitted,

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CERTIFICATE OF SERVICE

This is to certify that on this 22nd day of July, 2022, the foregoing Plaintiffs' Reply Brief was e-filed using the CM/ECF system.

Respectfully Submitted,
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